**CHAPTER II** 

## IN THE UNITED STATES ELECTED OFFICE (EO/US)

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE 19 JUNE 2001

PRIORITY DATE CLAIMED 7 SEPTEMBER 2000

PCT/US01/19546 TITLE OF INVENTION

NOVEL POLYMORPHIC FORM OF 17-β-(N-TER.BUTYL CARBAMOYL)-4-AZA-5-α-ANDROST-1-EN-3-ONE AND A PROCESS FOR PREPARING IT

APPLICANT(S)

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Mail Stop PCT Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

ATTENTION: EO/US

# COMPLETION OF FILING REQUIREMENTS FOR INTERNATIONAL APPLICATION ENTERING U.S. NATIONAL STAGE IN U.S. ELECTED OFFICE (EO/US) UNDER 35 U.S.C. § 371

(check and complete the applicable item, if applicable)

[X] This replies to the Notice of Missing Requirements under 35 U.S.C. § 371 and 37 C.F.R. § 1.495 (FORM PCT/DO/EO/905).

[X] A copy of FORM PCT/DO/EO/905 accompanies this response.

# **CERTIFICATION UNDER 37 C.F.R. 1.10\***

(Express Mail label number is mandatory.)
(Express Mail certification is optional.)

I hereby certify that this Completion of Filing Requirements and the papers indicated as being transmitted therewith are being deposited with the United States Postal Service on this date <u>March 15, 2004</u>, in an envelope as "Express Mail Post Office to Addressee," Mailing Label Number <u>EV 327552822 US</u>, addressed to the: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

(type oriprint name of person morting paper)

Signature of person mailing paper

WARNING:

Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

\*WARNING:

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Completion of Filing Requirements for International Application Entering U.S. Elected Office (EO/US)

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WARNING:

Where the items being submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (because international application papers are not covered by an ordinary certificate of mailing. 37 C.F.R. § 108(2)(xi).

NOTE:

Documents and fees must be clearly identified as a submission to enter the national stage under 35 U.S.C. § 371. Otherwise, the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.495(g).

#### **DECLARATION OR OATH**

NOTE: 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits . . . the oath or declaration of the inventor (35 U.S.C. 371(c)(4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17 (iv) within the time limits provided for in PCT Rule 26ter.1, applicant will be so notified and given a period of time within which to file the . . . oath or declaration in order to prevent abandonment of the application . . . . The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of thirty months after the priority date."

I. (a) [X] No original declaration or oath was filed.

#### OR

(b) [ ] The declaration or oath that was filed was determined to be defective. A new original oath or declaration is attached.

NOTE: For surcharge fee for filing declaration after filing date complete item IV(3)

NOTE:

- NOTE: Acceptable minimums in the declaration in an ordinarily filed U.S. application for identification of the specification to which it applies are:
- (A) application number (consisting of the series code and the serial number, e.g., 08/123,456);
- (B) serial number and filing date;
- (C) attorney docket number which was on the specification as filed;
- (D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or
- (E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.

M.P.E.P. § 602, 8th ed.

NOTE:

Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 C.F.R. § 1.10(c).

NOTE:

See 37 C.F.R. § 1.41(a).

(complete as applicable)

	Attac	hed is a				
	(a)	[ ]	Statement by practitioner that papers attached to decl those filed in PTO to get a filing date	aration are a copy of		
	(b)	[]	Statement that substitute specification contains no ne	w matter.		
	(c)	[]	Preliminary Amendment			
	(d)	[]	Submission of "Sequence Listing," computer readable amendment pertaining thereto for biotechnology invernucleotide and/or amino acid sequence			
			TRANSMITTAL OF ENGLISH TRANSLATION OF NON-ENGLISH LANGUAGE PAPERS	ı		
II.	[]	applic	Submitted herewith is an English translation of the non-English language international application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the PTO. (See 37 C.F.R. 1.495(c))			
NOTE:		For fee	for processing a non-English application, complete item IV(4).			
NOTE:		A non-English oath or declaration in the form provided or approved by the PTO need not be translated $37$ C.F.R. § $1.69(b)$ .				
m.			FEES			
	: See 37	C.F.R. § 1	.28(a).			
1.	Fees f	for claim	s			
	[]		ndependent claim in excess of 3 F.R. § 1.492(b))—\$86.00; small entity—\$43.00	\$		
	[]		laim in excess of 20 F.R. § 1.492(c))—\$18.00; small entity—\$9.00	\$		
	[]		ele dependent claims(s) F.R. § 1.492(d))—\$290.00; small entity—\$145.00	\$		
2.	Surch	arge fees	5			
	[]	the de	arge set forth in 37 C.F.R. § 1.492(e) for accepting claration later than 30 months after the priority date			
			ng an application in the U.S. as a designated —\$130.00; small entity—\$65.00	\$		
NOTE	Z:	The pro	ocessing fee in the next item 3 below is not subject to a reduction for s	small entity status.		

3.	[]	processing fee set forth in 37 C.F.R. § 1.492(f) for acceptance of an English translation later than 30 months after the priority date—\$130.00							
4.	[X]	fee for processing and retention of application (37 C.F.R. Sections 1.21(1) and 1.53(d)—\$130.00				\$	130.00		
				То	otal Fees			\$	130.00
			SMA	LL E	NTITY STA	TUS			
IV.	a.	[] AS	Statement or V	Vritten	Assertion tha	at this filing is	by a s	mall e	ntity
	NOTE:	See 37 C.F.R. § 1.28(a).							
		(check and complete applicable items)							
		[]	is attache was filed was mad	on	nying the bas	ic national fee	as a sı	mall ei	ntity.
	b.	[] As	eparate refund	i reque	st accompan	ies this paper.			
V. § 1.136	The pro	_	(complet	te (a) o	ION OF TIME TO (b), as application.	licable)	the pro	vision	s of 37 C.F.R.
	(a)								are set out in ked out below:
		Extension (months)			r other than			Fee fo	
	[]	one month		\$	110.00		\$	55.	00
	[]	two month	ıs	\$	420.00		\$	210.	00
	[ ]	three mon	ths	\$	950.00		\$	475.	00
	[]	four mont	ns	\$ 1	,480.00		\$	740.	00
NOTE: The 2-month time period for reply to A Notice to File Missing Parts of an Applie identified on the Notice as a statutory period subject to 35 U.S.C. 133. Thus, extup to 5 months under 37 CFR 1.136(a), followed by additional time under 37 Cappropriate, are permitted. MPEP 710.02(d)(c), 8th ed.					xtension	s of time of			
	[X]	five month	ıs	\$ 2	2,010.00		\$	1,005	.00
						Fee:	\$ 2	2,010.0	00

If an additional extension of time is required, please consider this a petition therefor. (check and complete the next item, if applicable) \_\_ months has already been secured. The fee paid therefor [] is deducted from the total fee due for the total months of extension now requested. Extension fee due with this request \$ or Applicant believes that no extension of term is required. However, this conditional (b) [ ] petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time. TOTAL FEE DUE VI. The total fee due is: Completion fee(s) \$ 2,010.00 Extension fee (if any) TOTAL FEE DUE \$ 2,140.00 **PAYMENT OF FEES** VII. Enclosed is a check in the amount of \$ 2,140.00 [X] Charge Account No. 12-0425 in the amount of \$ \_\_\_\_ [] A duplicate of this request is attached. Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. NOTE: § 1.22(b). AUTHORIZATION TO CHARGE ADDITIONAL FEES VIII. Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if **WARNING**: extra claims are authorized. NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3). "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a NOTE:

reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may

be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

[X] The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 12-0425

[X]  $37 \text{ C.F.R. } \{1.492(a)(1), 1.492(a)(4) \text{ (filing fees)}\}$ 

[ ] 37 C.F.R. § 1.492(b), (c), and (d) (presentation of extra claims)

NOTE:

Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

[X] 37 C.F.R. § 1.17 (application processing fees)

[X] 37 C.F.R.  $\S$  1.17(a)(1)-(5)(extension fees pursuant to  $\S$  1.136(a)).

Section 1.311(b) provides that an authorization to charge the issue fee (§ 1.18) to a deposit NOTE: account may be filed in an individual application only after the mailing of the notice of allowance, Accordingly, general authorizations to any fees and specific authorizations to pay the issue fee that are filed prior to the mailing of a notice of allowance will generally not be treated as requesting payment of the issue fee and will not be given effect to act as a reply to the notice of allowance. Applicant, when paying the issue fee, should submit a new authorization to charge fees, such as by completing box 6b on the current PTOL 85-B form. Where no reply to the notice of allowance is received, the application will stand abandoned notwithstanding the presence of general authorizations to pay fees or a specific authorization to pay the issue fee that were submitted prior to mailing of the notice of allowance. Where an attempt is made to pay the issue fee but an incorrect amount is submitted, § 1,311(b)(1), or where the Office's issue fee transmittal form (currently PTOL-85(B)) is completed by applicant ans submitted, § 1.311 (b)(2), in reply to a notice of allowance, an exception will be made. Such submissions will operate as a request to charge the issue fee to any deposit account identified in a previously filed (i.e., submitted prior to the mailing of the notice of allowance) authorization to charge fees, and will be allowed to act as payment of the correct issue fee. § 1.311(b). See also the change to § 1.26(b), Notice of September 8, 2000, Fed. Reg. 54603-54683, at 54646 and 54647.

[X] 37 C.F.R. § 1.492(e) and/or (f) surcharge fees for filing the declaration and/or an English translation of an international application later than 30 months from the earliest-claimed priority date.

**WARNING:** 

It would be wise to always check this last authorization.

Refund any overpayment to deposit account 12-0425.

SIGNATURE OF PRACTITIONER

Reg. No.: 33,778

JANET I. CORD

(type or print name of practitioner)

Tel. No.: (212)

LADAS & PARRY

P.O. Address

Customer No.: 00140

26 WEST 61<sup>ST</sup> STREET

NEW YORK, NEW YORK 10023



# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS PO. Box 1450 Alexandra, Virginia 22313-1450 www.usplo.gov

**371 FORMALITIES LETTER** 

\*OC000000010693924\*

**CONFIRMATION NO. 7747** 

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATT	Y. DOCKET NO.		
10/363,719	M. Satyanarayana Reddy	, ι	U 014451-1		
		INTERNATIONAL APPLICATION NO. PCT/US01/19546			
	_				
00140	RECEIVED C	I.A. FILING DATE	PRIORITY DATE		
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023	AUG 2 1 2003	06/19/2001	09/07/2000		

Lin Cit 10

Date Mailed: 08/15/2003

# NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 03/07/2003
- Copy of the International Search Report filed on 03/07/2003
- Copy of IPE Report filed on 03/07/2003
- Information Disclosure Statements filed on 03/07/2003
- Request for Immediate Examination filed on 03/07/2003
- Copy of references cited in ISR filed on 03/07/2003
- U.S. Basic National Fees filed on 03/07/2003

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

\$130 Late oath or declaration Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The tirne period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice **MUST** be returned with the response.

KAREN M WILLIAMS

Telephone: (703) 305-3688

# PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/363,719	PCT/US01/19546	U 014451-1

FORM PCT/DO/EO/905 (371 Formalities Notice)